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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,852	09/22/2000	Per Johan Lundberg	1103326-0686	1116

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WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER
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DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/646,852

Applicant(s)

LUNDBERG ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 12.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1615

### **DETAILED ACTION**

Receipt of Applicant's request for continued examination, filed on March 3, 2003, is acknowledged.

#### ***Specification***

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (EP 0237200) in view of Okada et al. (JP402237918) or Preston et al. (U.S. Patent 5,776,489).

The claimed invention refers to an oral pharmaceutical dosage form of omeprazole comprising a core coated with a membrane, process of making and method of administering said dosage form.

Art Unit: 1615

Makino et al. discloses pharmaceutical compositions of benzimidazole derivatives, including omeprazole, said compositions prepared by mixing the drug with basic inorganic salts and additives, including vehicles such as sucrose (an osmotic agent) and cellulose, binders such as hydroxypropylcellulose and PVP, and lubricants, such as talc (See p. 8, lines 14-23). Makino et al. teaches that the mixture can be made up into dosage forms, such as tablets and capsules and the tablets may be coated by known methods to mask the taste or provide the dosage forms with sustained release properties, and includes ethyl cellulose and cellulose acetate among the coating agents used in the invention (See p. 8, lines 34-41). Makino et al. contemplates both enteric and sustained release polymer coatings, however, one of ordinary skill in the art interested in providing the formulations of the invention with sustained release properties, would have been guided by the teachings of Makino et al. to select water-insoluble polymers, such as ethyl cellulose, rather than enteric polymers, to provide the dosage forms with said release properties. Makino et al. does not specify the amount of each additive in the formulations of the invention, however, one of ordinary skill in the art would have been able to determine the optimal concentration of each additive by routine experimentation. Makino et al. is deficient in the fact, that it does not specifically teach that the coating may comprise a modifying agent.

Okada et al. provides a long acting coating film comprising ethyl cellulose and talc for sustained release formulations.

Art Unit: 1615

Preston et al. provides granules coated with film forming polymers and includes Surelease, a commercial coating comprising ethyl cellulose and fumed silica, among the coatings useful in the invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Makino et al. to device sustained release dosage forms of omeprazole, and include in the coating a modifying agent, as taught by Okada et al. or Preston et al., to improve the response to changes in environment pH . The expected result would have been a successful dosage form of omeprazole and successful methods of manufacturing and administering said dosage form . Because of the teachings of Makino et al., that sustained release pharmaceutical compositions of omeprazole exhibit excellent gastric anti-secretory and anti-ulcer activities, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

#### ***Response to Arguments***

4. Applicant's arguments filed on March 3, 2003, have been fully considered but they are not persuasive.

5. Applicant argues that it has been the art-recognized practice to apply an enteric coating layer to oral dosage forms of omeprazole and submits documents in support of Applicant's

Art Unit: 1615

argument, that Makino et al. did not contemplate or suggest oral formulations without an enteric coating. The examiner has considered said documents, however, as asserted in the previous Office action, it is noted that Makino et al. clearly contemplates both sustained release and enteric coatings (See p. 8, lines 34-41), and includes ethyl cellulose, which is a water-insoluble polymer, among the coating agents used in the invention, thus providing the general teachings that formulations of omeprazole may be coated with ethyl cellulose to provide sustained release oral dosage forms. One of ordinary skill in the art would have been guided to select the coating agents, which provide sustained release properties, by the teachings of Makino et al. Therefore, it would have been obvious to one of ordinary skill in the art to apply the teachings of Makino et al. to device a dosage form of omeprazole comprising an ethyl cellulose coating.

6. In response to Applicant's argument, that the delayed release of the claimed dosage form is different from the sustained release disclosed by the prior art, it is noted that the instant claims do not read on a delayed release and do not include the limitations shown in Example 4 of the specification and cited by Applicant. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. In response to Applicant's argument, that Makino et al. fails to disclose modifying agents in the membrane, the examiner relies on the teachings of Okada et al. and Preston et al. to show that modifying agents are routinely mixed with ethyl cellulose to provide film coatings in sustained release formulations.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on

Art Unit: 1615

obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

Claims 1, 3-20 and 23-27 stand rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.



April 1, 2003



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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